

Prescription Label

Patient Name:

Species:

Drug Name & Strength:

Directions (amount to give how often & for how long):

Prescribing Veterinarian's Name & Contact Information:

Refills:

[Content to be provided by prescribing veterinarian]

Spinosad

(*spin-oh-sad*)

Description: Flea Adulticide

Other Names for this Medication: Comfortis®

Common Dosage Forms: Veterinary: Chewable tablets: 90 mg, 140 mg, 270 mg, 560 mg, 810 mg, & 1620 mg. **Human:** None as oral products; topical forms are available.

This information sheet does not contain all available information for this medication. It is to help answer commonly asked questions and help you give the medication safely and effectively to your animal. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- ▶ Spinosad is an oral tablet given monthly that kills adult fleas on dogs and cats; it begins to kill fleas 30 minutes after dosing. This product does not kill ticks.
- ▶ Give medication with food.
- ▶ When used as directed on the label, this medication appears safe.
- ▶ Product can be harmful to wildlife, so dispose of unused drugs carefully.
- ▶ Keep chewable tablets well out of reach of children and animals.

How is this medication useful?

Spinosad is given by mouth to dogs and cats to prevent and treat flea infestations. The FDA (U.S. Food & Drug Administration) has approved this drug to prevent and treat flea infestations for 1 month in dogs at least 14 weeks of age that weigh at least 3.3 pounds and in cats that are at least 14 weeks of age and weigh at least 2 pounds. The FDA allows veterinarians to prescribe and use products containing this drug in different species or for other conditions in certain situations. You and your veterinarian can discuss why this drug is the most appropriate choice.

What should I tell my veterinarian to see if this medication can be safely given?

Many things might affect how well this drug will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- ▶ Other drugs can interact with this drug, so be sure to tell your veterinarian and pharmacist what medications (including vitamins, supplements, or herbal therapies) you give your animal, including the amount and time you give each.

- ▶ Tell your veterinarian about any conditions or diseases your animal may have now or has had in the past.
- ▶ If your animal has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how well it did or didn't work.
- ▶ If your animal is pregnant or nursing, talk to your veterinarian about the risks of using this drug.
- ▶ Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching, hair loss) your animal has developed in the past.

How long until I will know if this medication is working, and how long will the effects of this medication last?

Fleas will begin to die within 4 to 8 hours. Your animal's clinical signs should begin to improve after that time. The effects of this medication are long-lived, meaning they may last for multiple (ie, 4 to 6) weeks, although they may be prolonged if your animal has decreased kidney and/or liver function.

When should this medication not be used or be used very carefully?

No drug is 100% safe in all patients, but your veterinarian will discuss with you any specific concerns about using this drug in your animal.

This drug **SHOULD NOT** be used in patients:

- ▶ That are allergic to it.

This drug should be used **WITH CAUTION** in:

- ▶ Animals with a seizure disorder (eg, epilepsy).
- ▶ Cats: Less than 14 weeks of age or that weigh less than 2 pounds; safe use in these animals has not been determined.
- ▶ Dogs: Less than 14 weeks of age or that weigh less than 3.3 pounds; safe use in these animals has not been determined.
- ▶ Animals receiving higher doses of a drug called ivermectin.

If your animal has any of these conditions, talk to your veterinarian about the potential risks versus benefits.

What are the side effects of this medication?

Spinosad is normally tolerated well and side effects are rare.

Common but not serious side effects include:

- ▶ Vomiting, diarrhea.
- ▶ Excessive salivation (drooling).
- ▶ Itching.
- ▶ Trembling.
- ▶ Lack of energy.
- ▶ Reduced appetite.

You don't have to be overly concerned if you see any of these signs unless they are severe, worsen, or continue to be a problem. Contact your veterinarian if this happens.

Side effects that may be serious or indicate a serious problem:

- ▶ Stumbling, incoordination, weakness.
- ▶ Seizures (convulsions).

If you see any of these signs, contact your veterinarian immediately.

If my animal gets too much of this medication (an overdose), what should I do?

If you witness or suspect an overdose, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers that are open 24 hours a day include **Pet Poison HELPLINE** (855-764-7661) and **ASPCA Animal Poison Control Center** (888-426-4435); a consultation fee is charged for these services.

How should this medication be given?

For this medication to work, give it exactly as your veterinarian has prescribed. It's a good idea to always check the prescription label to be sure you are giving the drug correctly.

- ▶ Spinosad is given monthly when used for flea control.
- ▶ Dogs usually willingly eat the chewable tablets when offered them just before feeding, and cats willingly take before or after feeding. Alternatively, tablets can be mixed in food or given like other tablet medications.
- ▶ If vomiting occurs within an hour of administration, you can give another full dose.

- ▶ Compounded liquid forms of this medication must be measured carefully. Your veterinarian or pharmacist can help by providing special measuring spoons or syringes.
- ▶ If you have difficulty getting your animal to take the medicine, contact your veterinarian or pharmacist for tips to help with dosing and reducing the stress of medication time.
- ▶ This medication can be given for various lengths of time. Be sure you understand how long your veterinarian wants you to continue giving this medication. Prescription refills may be necessary before the therapy will be complete. Before stopping this medication, talk to your veterinarian, as there may be important reasons to continue its use.

What should I do if I miss giving a dose of this medication?

If you miss a dose, give it when you remember, and then wait the amount of time between doses recommended by your veterinarian before giving another dose. Do not double-up or give extra doses.

How should I store this medication?

- ▶ Store this medication in the original prescription container or an approved dosage reminder container (ie, pill minder) at room temperature and protected from light.
- ▶ If your veterinarian or pharmacist has made (compounded) a special formulation for your animal, follow the storage recommendations and expiration date for the product.
- ▶ Keep away from children and other animals.

Can handling this medication be hazardous to me, my family, or other animals?

There are no specific precautions required when handling this medication unless you are allergic to it. Wash your hands after handling any medication.

How should I dispose of this medication if I don't use it all?

- ▶ Do not flush this medication down the toilet or wash it down the sink. If a community drug “take-back” program is available, use this option. If there is no take-back program, mix the drug with coffee grounds or cat litter (to make it undesirable to children and animals and unrecognizable to people who might go through your trash), place the mixture in a sealable plastic bag to keep it from leaking out, and throw the bag out with the regular trash.
- ▶ Do not save leftover medication for future use or give it to others to use.

What other information is important for this medication?

- ▶ Treatment with spinosad may begin at any time of the year but should preferably start 1 month before fleas become active and continue monthly through the end of flea season. In areas where fleas are common, year-round, monthly treatment should continue year round without stopping.
- ▶ To reduce the chance of flea reinfestation, all animals in the household must be treated with an approved flea protection product.
- ▶ Use of this drug may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.

If you have any other questions about this medication, contact your veterinarian or pharmacist.

Special Instructions: <hr/> <hr/> <hr/> <hr/>
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Refills:

[Content to be provided by prescribing veterinarian]

Spinosad with Milbemycin

(*spin-oh-sad* with *mil-beh-my-sin*)

Description: Heartworm Preventive; Agent to Treat and Control Intestinal Parasites; Kills Adult Fleas

Other Names for this Medication: Trifexis®

Common Dosage Forms: Veterinary: (Spinosad/Milbemycin) 140 mg/2.3 mg, 270 mg/4.5 mg, 560 mg/9.3 mg, 810 mg/13.5 mg, & 1620 mg/27 mg flavored oral tablets. **Human:** None.

This information sheet does not contain all available information for this medication. It is to help answer commonly asked questions and help you give the medication safely and effectively to your animal. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

Key Information

- ▶ Oral combination product given monthly to kill adult fleas, prevent heartworm infection, and control hookworms, roundworms, and whipworms in dogs. This combination product does not kill ticks.
- ▶ Give medication with food.
- ▶ When used as directed by the label, spinosad with milbemycin appears safe.
- ▶ This drug combination can be harmful to wildlife, so dispose of unused drugs carefully.
- ▶ Keep chewable tablets well out of reach of children and animals.

How is this medication useful?

Spinosad with milbemycin is given for the prevention of heartworm disease, prevention and treatment of flea infestations, and the treatment and control of hookworm, roundworm, and whipworm infections in dogs and puppies 8 weeks of age or older that weigh at least 5 pounds. The FDA (U.S. Food & Drug Administration) has approved this drug combination for use in dogs. The FDA allows veterinarians to prescribe and use products containing this drug in different species or for other conditions in certain situations. You and your veterinarian can discuss why this drug is the most appropriate choice.

What should I tell my veterinarian to see if this medication can be safely given?

Many things might affect how well this drug will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.

- ▶ Other drugs can interact with this drug combination, so be sure to tell your veterinarian and pharmacist what medications (including vitamins, supplements, or herbal therapies) you give your animal, including the amount and time you give each.

- ▶ Tell your veterinarian about any conditions or diseases your animal may have now or has had in the past.
- ▶ If your animal has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how well it did or didn't work.
- ▶ If your animal is pregnant or nursing, talk to your veterinarian about the risks of using this drug.
- ▶ Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching, hair loss) your animal has developed in the past.

How long until I will know if this medication is working, and how long will the effects of this medication last?

Fleas will begin to die within 4 to 8 hours. This medication should start having effects on other parasites within 1 to 2 days. Your animal's clinical signs should begin to improve after that time. The effects of this medication are long-lived, meaning they may last for multiple (ie, 4 to 6) weeks, although they may be prolonged if your animal has decreased kidney and/or liver function.

When should this medication not be used or be used very carefully?

No drug is 100% safe in all patients, but your veterinarian will discuss with you any specific concerns about using this drug in your animal.

This drug **SHOULD NOT** be used in patients:

- ▶ That are allergic to spinosad, milbemycin, or other avermectin drugs (eg, ivermectin, selamectin).

This drug should be used **WITH CAUTION** in patients:

- ▶ That have not been tested for heartworm infection. Shock-like reactions can occur if milbemycin is given to animals with heartworm infection.
- ▶ That are pregnant, nursing, or used for breeding; safe use in these animals has not been determined.
- ▶ With a seizure disorder (eg, epilepsy).
- ▶ Less than 8 weeks old and that weigh less than 5 lb (dogs); safe use in these animals has not been determined.

If your animal has any of these conditions, talk to your veterinarian about the potential risks versus benefits.

What are the side effects of this medication?

In dogs, spinosad with milbemycin is usually tolerated well.

Common but not serious side effects include:

- ▶ Vomiting, diarrhea.
- ▶ Excessive salivation (drooling).
- ▶ Itching.
- ▶ Trembling.
- ▶ Depression, lack of energy.
- ▶ Reduced appetite.
- ▶ Skin reddening.

You don't have to be overly concerned if you see any of these signs unless they are severe, worsen, or continue to be a problem. Contact your veterinarian if this happens.

Side effects that may be serious or indicate a serious problem:

- ▶ Stumbling, incoordination, weakness.
- ▶ Seizures (convulsions).

If you see any of these signs, contact your veterinarian immediately.

If my animal gets too much of this medication (an overdose), what should I do?

If you witness or suspect an overdose, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers that are open 24 hours a day include **Pet Poison HELPLINE** (855-764-7661) and **ASPCA Animal Poison Control Center** (888-426-4435); a consultation fee is charged for these services.

How should this medication be given?

For this medication to work, give it exactly as your veterinarian has prescribed. It's a good idea to always check the prescription label to be sure you are giving the drug correctly.

- ▶ The spinosad with milbemycin combination product is given once a month.
- ▶ The chewable tablets are usually willingly eaten by dogs when offered just before feeding. Alternatively, the tablets can be mixed in food or given like other tablet medications.
- ▶ If vomiting occurs within an hour of administration, re-dose with another full dose.

- ▶ If you have difficulty getting your animal to take the medicine, contact your veterinarian or pharmacist for tips to help with dosing and reducing the stress of medication time.
- ▶ This medication can be given for various lengths of time. Be sure you understand how long your veterinarian wants you to continue giving this medication. Prescription refills may be necessary before the therapy will be complete. If you want to stop giving this medication, talk to your veterinarian, as there may be important reasons to continue giving it.
- ▶ Treatment with fewer than 3 monthly doses after the last exposure to mosquitoes may not provide heartworm prevention.

What should I do if I miss giving a dose of this medication?

- ▶ If you miss a dose, give it when you remember and then wait the amount of time between doses recommended by your veterinarian before giving another dose. Do not double-up or give extra doses.
- ▶ When using this product for heartworm prevention, if more than 8 weeks have passed without giving this medication, start giving the drug as soon as you remember. After that, continuing giving the medication monthly, but make sure to have your animal tested for heartworm infection 6 months later, as your dog may have become infected during the time the medication was not given.

How should I store this medication?

- ▶ Store this medication in the original prescription bottle or an approved dosage reminder container (ie, pill minder) at room temperature and protected from light.
- ▶ If your veterinarian or pharmacist has made (compounded) a special formulation for your animal, follow the storage recommendations and expiration date for the product.
- ▶ Keep chewable tablets well out of reach of children and animals.

Can handling this medication be hazardous to me, my family, or other animals?

There are no specific precautions required when handling this medication unless you are allergic to it. Wash your hands after handling any medication.

How should I dispose of this medication if I don't use it all?

- ▶ Dispose of spinosad with milbemycin carefully, as it can be toxic to wildlife.
- ▶ Do not flush this medication down the toilet or wash it down the sink. If a community drug “take-back” program is available, use this option. If there is no take-back program, mix the drug with coffee grounds or cat litter (to make it undesirable to children and animals and unrecognizable to people who might go through your trash), place the mixture in a sealable plastic bag to keep it from leaking out, and throw the bag out with the regular trash.
- ▶ Do not save leftover medication for future use or give it to others to use.

What other information is important for this medication?

- ▶ Treatment with spinosad with milbemycin may begin at any time of the year, preferably starting 1 month before fleas or mosquitos become active and continuing monthly through the end of mosquito or flea season. In areas where fleas or mosquitos are common year-round, monthly treatment should continue the entire year without stopping.
- ▶ To reduce the chance of flea reinfestation, all animals in the household must be treated with an approved flea protection product.
- ▶ Use of this drug may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.

If you have any other questions about this medication, contact your veterinarian or pharmacist.

Special Instructions: _____ _____ _____ _____
